

**REMARKS/ARGUMENTS**

Claims 6-16 remain in this application. Applicant respectfully requests entry of the above specification and claim amendments and submits that these amendments do not comprise new matter.

**New Matter Objection**

The Office Action states that the amendment to page 9, filed December 10, 2002, is objected to under 35 U.S.C. § 132 as allegedly adding new matter. Specifically, the Office Action objects to the last sentence of the the second paragraph on page 9. Applicant respectfully submits that this last sentence does not comprise new matter. However, without conceding that the last sentence comprises new matter, Applicant has deleted the last sentence of the second paragraph on page 9 of the specification. Accordingly, Applicant respectfully submits that the new matter objection is moot.

**Rejections under 35 U.S.C. § 112, First Paragraph**

The Office Action states that claims 1-16 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Specifically, the Office Action states that claims 1-16 are rejected for the reasons provided in the New Matter Objection.

As discussed above, Applicant has deleted the last sentence of the second paragraph on page 9 of the specification. Accordingly, Applicant respectfully submits that the rejection under 35 U.S.C. § 112, first paragraph, is moot in view of the deletion of this last sentence.

**Rejections under 35 U.S.C. § 112, Second Paragraph**

The Office Action states that claims 11 and 12 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly

claim the subject matter which Applicant regards as the invention. Specifically, the Office Action states that the phrase "capable of" is not clear. In accordance with the Examiner's suggestion, Applicant has amended claim 11 to delete the phrase "capable of." As such, Applicant respectfully submits that this amendment obviates the rejection of claims 11 and claim 12.

**Rejections under 35 U.S.C. § 102(b)**

The Office Action states that claims 1-16 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Takata et al. (Cardiovascular Research, 32, 286-293, 1996).

Upon entry of the above claim amendments, claims 1-5 are cancelled, without prejudice or disclaimer to the subject matter therein. Accordingly, Applicant respectfully submits that the rejections of claims 1-5 are moot.

With regard to the rejections of claims 6-16, Applicant respectfully traverses the rejections.

Anticipation, of course, requires that a single reference disclose each element of the claim under consideration either explicitly or under principles of inherency. In the present case, Applicant respectfully contends that the subject matter, as recited by the claims of the present invention, is distinguished from the disclosure of Takata et al. as Takata et al. does not disclose or even remotely suggest any method which can reduce an infarct region or suppress enlargement of an infarct region. At most, the cardioprotective effect of ANP disclosed by Takata et al. is simply the suppression of arrhythmia such as ventricular extrasystoles or the suppression of the decrease of intra-cellular high-energy phosphates. However, suppression of arrhythmia and/or suppression of the decrease of intra-cellular high-energy phosphates are distinguished from the reduction of an infarct region, such as is recited in the independent claims of the present invention. As such, Takata et al. fails to meet the requirements for anticipation as

Takata et al. does not reach all the elements and limitations recited in the claims of the present invention.

The Office Action states that Takata et al. allegedly anticipates claims 6-10 by teaching a method of cardioprotection . . . of myocardial ischemia . . . and reperfusion . . . by administering a composition comprising an effective amount of synthetic alpha human ANP (atrial natriuretic peptide) . . . , which increases the level of cyclic guanosine monophosphate (cGMP) . . . , and has cardioprotective effects on myocardial ischemia and reperfusion injury. However, it is clear that by the method of claim 6, an infarct region is reduced by administering a substance which can increase intracellular cGMP production by acting on a natriuretic peptide receptor, and which has an effect of reducing an infarct region. The administration, as recited in claim 6, is made in relation to ischemia reperfusion therapy (i.e., before the initiation of, during and/or following ischemia reperfusion therapy).

In contrast, Takata et al. does not mention, disclose, or teach the reduction of an infarct region. In fact, Takata et al. explicitly teaches away from treating an infarct region by instead disclosing and teaching methods of preventing the myocardial ischemic event from even occurring. Alternatively, even if Takata et al. could be found to implicitly or inherently teach treatment of infarct regions (as opposed to the prevention of infarct regions that are explicitly taught and disclosed), Takata et al. still fails to anticipate the claims of the present invention as Takata et al. fails to appreciate that the methods disclosed in Takata et al. might treat infarct regions.

With regard to claim 11 of the present invention, the distinguishing feature of reducing an infarct region or suppressing enlargement of an infarct region in the heart is recited even more specifically. However, the Office Action does not state a clear or specific reason why claims 11-16 are considered anticipated by Takata et al. If—even in view of the above claim amendments and remarks—the Examiner still considers these claims anticipated by Takata et al., Applicant respectfully requests further elaboration as to the reasoning behind the continued

anticipation rejection so that Applicant may better address any such reasoning to explain why the present invention distinguishes over Takata et al.

For at least the foregoing reasons, Applicant respectfully submits that the present invention distinguishes over Takata et al. Applicant respectfully requests removal of the rejections of claims 6-16 under 35 U.S.C. § 102(b).

### CONCLUSION

Applicant respectfully requests entry of the above claim amendments. In view of the above amendments and remarks, early notification of a favorable consideration is respectfully requested. Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned, at the telephone number listed below, to conduct an interview in an effort to expedite prosecution in connection with the present application. The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 50-0206.

Respectfully submitted,

Dated: Oct 22, 2003

By: David H. Milligan

Robert M. Schulman  
Registration No. 31,196  
David H. Milligan  
Registration No. 42,893

HUNTON & WILLIAMS LLP  
Intellectual Property Department  
1900 K Street, N.W.  
Suite 1200  
Washington, DC 20006-1109  
(202) 955-1500 (telephone)  
(202) 778-2201 (facsimile)